NEW YORK STATE SOCIETY FOR MEDICAL RESEARCH 2 EAST 63rd STREET, NEW YORK N. Y. 10021 212-TE 8 6120

CODE: Hill Bill Solid underline

Javits Bill. No marks

New Additions. Broken underline

A BILL

To among the Public Health Service Act to provide special
assistance for the improvement of laboratory animal facilities; to esuablish standards for the humane care, handling, and treatment of laboratory animals in departments, agencies, and instrumentalities of the United States and by recipients of grants, awards, and contracts from the United States; to encourage the study and improvement of the care, handling, and treatment and the development of methods for minimizing pain and discomfort of animals used in research, training, or testing; and to otherwise assure humane care, handling, and treatment of laboratory animals.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Humane Laboratory Animal Treatment Act of 1966".

DECLARATIONS OF POLICY

SEC. 2. The Congress hereby finds and declares that healthy laboratory animals of high quality are essential to the conduct of research, training, and testing activities vital to the health and safety of the people of the United States, and that animals used in research, training, and testing should be spared unnecessary pain and discomfort.

DEFINITIONS

- SEC. 3. For the purposes of this Act--
- (1) The terms "department or agency" and "department and agency" mean any department, agency, or instrumentality of the United States.
- (2) The term "Secretary" means the "Secretary of Health, Education and Welfare.
- (3) The term "laboratory" means any organization, institution, school, corporation, partnership, association, or individual engaged in scientific research, training, or testing which involves the use of animals.
- (4) The term "laboratory supported by Federal funds"
 means any laboratory (A) receiving a grant or award from,
 having a contract with, or otherwise receiving funds from
 any department or agency, or (B) which is used by one or more

individuals engaged in research and receiving a grant or award from, having a contract with, or otherwise receiving funds from any department or agency.

- (5) The term "person" means any individual, partnership, association, or corporation.
- (6) The terms "laboratory animal" and "animal" mean any living vertebrate animal which is used or intended for use in connection with scientific research, training, or testing.
- (7) The term "accredited" means a laboratory accredited by the Secretary or by any professional body or bodies which have been approved for such purpose by the Secretary after consultation with departments and agencies and organizations referred to in section 5 of this Act.

GRANTS FOR CONSTRUCTION OF LABORATORY ANIMAL FACILITIES

- SEC. 4. So much of section 706(a) of the Public Health Service Act (relating to the amount of grants for construction of health research facilities), as follows the semicolon is amended to read as follows: "except that--
 - (1) in the case of a grant for construction of any facility which the Secretary determines is to be used

(primarily or exclusively) as a laboratory animal facility for research, or research and purposes related thereto (including research training), in the sciences related to health, such amount may not exceed 66-2/3 per centum of the necessary cost of construction as determined by the Secretary, but the total of the grants for any fiscal year to which this clause applies may not exceed 25 per centum of the sums appropriated for grants under this part for such year;

"(2) in the case of any other great for a facility which
the Secretary determines is to be used for research, or research and purposes related thereto (including research
training), in the sciences related to health, such amount may
not exceed 50 per centum of the necessary cost of construction, as determined by him, or, in the case of a multipurpose
facility, 50 per centum of the part of the necessary cost of
construction which he determines to be proportionate to the
contemplated use of the facility for research, or research
and related purposes, in the sciences related to health."

STANDARDS AND REGULATIONS

SEC. 5. In order to effectuate the findings and declarations set forth in section 2 of this Act, the <u>Secretary</u> shall prescribe and publish in the Federal Register standards and regulations

for the humane care, handling, and treatment of laboratory animals, and for the accreditation of laboratories. In formulating such standards and regulations the Secretary shall consult with (1) departments and agencies which use laboratory animals or which make grants, awards, or contracts involving their use by the recipients of such grants, awards, or contracts, (2) the National Academy of Sciences-National Research Council, (3) such other scientific organizations as he may select, and (4) such private nonprofit organizations as he may select that are primarily concerned with the humane care and treatment of animals, Such standards and regulations shall conform to the requirements prescribed below:

- (1) All laboratories supported by Federal funds shall be accredited and their premises and facilities shall be periodically inspected by the accrediting agency and by the Secretary or by qualified representatives of the Secretary.
- (2) All laboratories supported by Federal funds shall provide for the review of policies and procedures governing the care, handling and treatment of laboratory animals in such laboratory enimal facilities, for the purpose of ascuring that laboratory animals are used in such facilities only for legitimate scientific or educational purposes, and that

in the care, handling and treatment of laboratory animals in such facilities, including policies and procedures designed to protect the animals against unnecessary pain and suffering, and such review is made by a committee on animal care and utilization composed of two or more scientists associated with such facilities, or with the organization or institution of which such facilities are a part.

- (3) Commensurate with the experimental needs and with the physiological functions under study, all research, training, or testing likely to cause pain or discomfort, shall be performed under adequate anesthesia;
- (4) When a surgical operation is to be performed on any animal, conditions and care shall be observed during and after the operation, consistent with good surgical and veterinary practice, to minimize post-operative discomfort and infection;
- (5) Each animal shall receive proper provision for its bodily comfort and each animal shall be humanely treated, properly fed and watered, and housed and transported in sanitary quarters with space and facilities appropriate to its species. No animal shall be permitted to experience pain or discomfort through neglect or mishandling;

(6) Records relating to the use and disposition of all animals shall be maintained in such form and in such manner as to make possible the evaluation of compliance with the requirements of this Act.

COMPLIANCE

- SEC. 6. On and after the ninetieth day after the exendends and regulations provided for in section 5 of this Act are published in the Federal Register--
 - (1) All departments and agencies which use laboratory enimals shall comply with such standards and regulations.
 - (2) No grant, award, or contract which involves the use of laboratory animals shall be made by any department or agency unless the recipient thereof is accredited and agrees in writing to (A) comply with the standards and regulations prescribed and published under section 5 of this Act, (B) permit such inspections of its premises and facilities by Covernment inspectors as may be prescribed in such regulations or as the Secretary deems necessary in order to determine whether such standards are being met by the recipient, and (C) file such reports as may be prescribed by the regulations.

- (3) If the Secretary determines that the recipient of any grant, award, or contract has failed to comply with clauses (A), (B), and (C) of paragraph (2) of this section, he shall notify such recipient specifying the nature of such noncompliance and the time within which the noncompliance shall be remedied; any department or agency shall discontinue payments under any grant or award, and cancel any contract made after the effective date of this section, if the recipient thereof fails to comply with clause (A), (B), or (C) of paragraph (2) of this section within the time specified in the notice.
- (4) If the Secretary determines that an applicant is incligible for a grant, award, or contract because of a failure to comply with the requirements of clause (A), (E), or (C) of paragraph (2) of this section, such applicant shall remain incligible until evidence of compliance with such requirements has been established to the satisfaction of the Secretary, and if a department or agency has discontinued payments to the recipient of a grant or award or has canceled a contract because of a failure to comply with such requirements, no payments to the recipient shall be resumed nor shall the contract be renewed until evidence of compliance

with such requirements has been established to the satisfaction of the Secretary.

FINANCIAL ASSISTANCE

- SEC. 7. (a) The Secretary shall encourage research and make funds available for training of individuals in laboratory animal care, the improvement and development of laboratory methods and techniques, the fabrication of instruments, humane methods for the care, handling and treatment of laboratory animals, and the design and construction of custodial facilities for laboratory animals, and may make grants and set up centers for such purposes.
- (b) The Secretary is authorized to make, on such terms and conditions as he may deem appropriate, grants to or contracts with any body approved by him, to assist in meeting the costs of such body in carrying out the function of accreditation provided for in this Act.

TECHNICAL ASSISTANCE AND DISSEMINATION OF INFORMATION

SEC. 8. The <u>Secretary</u> shall collect and make available through publications, conferences, films, demonstrations, and other appropriate means, information relating to the humane care, treatment, and handling of laboratory animals used for research.

training, or testing purposes; including the proper use of chesthesia, design and analysis of experiments, selection of the biological model, and the effective use of informational tools; and, insofar as possible, shall provide technical assistance with respect to the means of providing and training the personnel necessary to assure such care, treatment, and handling to departments or agencies, persons, laboratories, and other entities.

PENALTIES

SEC. 9. Any person guilty of violating any provision of this Act shall be fined not more than \$1,000 or imprisoned not more why than one year, or both.

JUDICIAL REVIEW

SEC. 10. (a) Any party aggrieved by any determination made by the Secretary under section 5 or 6 of this Act shall be entitled to a judicial review of the basis for such determination by filing a written petition for an order setting aside that determination in the United States Court of Appeals, for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides and serving a true copy of the petition upon the Secretary, within sixty days after notice of such determination. The Secretary

thereupon shall certify and file in the court a true and correct transcript of the entire record of the proceedings upon which the determination was based, including all evidence taken and the findings and conclusions made by the Secretary thereon. The court shall have jurisdiction to hear and determine any such potition, and shall have power to affiliat, modify, or set aside the determination of the Segmetary. In any such review, the findings of fact made by the Georgeony, if supposed by substantial evidence, shall be conclusive. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such addithonal evidence is material, the court may order such additional evidence to be taken by the Secretary and to be considered in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts by reason of the additional cylience to taken, and he shall file such modified or new findings, and recommendations, if any, which, if supported by substantial evidence, shall be conclusive with respect to action in the watter under consideration. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

- (b) Any determination made by the Secretary under the provisions referred to in subsection (a) of this section shall become final--
 - (1) upon the expiration of the time allowed for filing a petition for judicial review, if no such petition has been duly filed within such time; or
 - (2) upon the expiration of the time allowed for filing a petition for certiorari if the determination of the Secretary has been affirmed or the petition for judicial review has been dismissed by a United States court of appeals, and no petition for certiorari has been duly filed; or
 - (3) upon the denial of a petition for certiorari, if the determination of the <u>Secretary</u> has been affirmed or the petition for review has been dismissed by a United States court of appeals; or
 - (4) upon the expiration of ten days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the determination of the Secretary be affirmed or that the petition for review be dismissed.

SAVINGS CLAUSE

SEC. 11. If any provision of this Act or the application thereof to any person, department or agency, or to any circumstance

shall be held invalid, the remainder of the Act and the application of any such provision to persons, departments, agencies, or circumstances other than those as to which it is held invalid shall not be affected thereby.

EFFECT OF REORGANIZATION PLAN

SEC. 12. The provisions enacted by this Act shall be subject to the provisions of Reorganization Plan Numbered 3 of 1946.

EFFECTIVE DATE

SEC. 13. This Act shall take effect one hundred and eighty days after enactment.